Clinical Evaluation Projects

Project Num	Project Name	Leader	Functional Area	Disease Area	Priority	Guidance/Evaluation/Publication	
N01154	ETS Exposure and Biomarkers of Exposure in the Total Exposure Study (TES)	Lau, R	Clinical Evaluation	ETS, CE Specific, Det of Exp	Priority	Evaluation	
N01320	A Model of Adult Smoking to Assess Exposure	Adams, C	Clinical Evaluation	Det of Exp	Priority	Guidance	
N01337	Multi-Center Total Exposure Study	Roethig, H	Clinical Evaluation	CVD, COPD, Det of Exposure, ETS, CE Specific	Critical	Guidance/Evaluation	
N01351	Exhaled Breath Measurements in Humans	~~Major, T~~ PM.	Clinical Evaluation	COPD, CE Specific	~~Priority~~	Evaluation	in plate
N01401	Exercise Performance of Adults Smoking ACCORD or Conventional Cigarettes	Unverdorben, M.	Clinical Evaluation	CVD	Critical	Evaluation	
N01402	Influence of Smoking the EHCSS ACCORD® on Endothelium-Dependent Venoreactivity	Unverdorben	Clinical Evaluation	CVD	Critical	Evaluation	
N01454	Knowledge and Quality Management for Clinical Evaluation	Kinser, R	Clinical Evaluation	CE Specific SAC	Critical	Guidance/Evaluation	
N01455	Assessment of exercise performance of non/no-smokers exposed to ETS	Unverdorben, M.	Clinical Evaluation	CVD, ETS. CE Specific	Priority	Guidance/Evaluation	
N01456	Non-linear modeling of biomarkers from the Multi-Center Total Exposure Study	Nelson, B	Clinical Evaluation	CE Specific	Priority	Evaluation	
N01457	Method Development for the Long Term Studies	Nelson, B	Clinical Evaluation	Det of Exp, CE Specific	Critical	Evaluation	
N01458	Method development for retention study	Feng, S.	Clinical Evaluation	CE Specific	Critical	Guidance/Evaluation	
N01459	TES Follow-up Study	Oey, J	Clinical Evaluation	CE Specific	Critical	Guidance/Evaluation	
N01460	Characterization of enzyme induction as an early biomarker of potential harm	Sarkar, M.	Clinical Evaluation	CE Specific, Cancer	Priority	Guidance/Evaluation	upate R
N01461	Population Exposure Biomarkers	Sarker, M.	Clinical Evaluation	CE Specific	Critical	Guidance	OD
N01462	Review of NCI database and other literature for functional genomics and/or proteomic studies characterizing early biomarkers for lung cancer	Sarkar, M.	Clinical Evaluation	CE Specific	Critical	Guidance	ongoing
N01464	~~Sputum cytology~~ and buccal Swabs DAL	Mendes, P.	Clinical Evaluation	COPD, CE Specific	Priority	Guidance/Evaluation	
N01465	Mucociliary Clearance (MCC)	Mendes, P.	Clinical Evaluation	CE Specific, COPD	Priority	Evaluation	
N01466	~~Early Biomarkers of Inflammation~~	~~Mendes, P.~~	~~Clinical Evaluation~~	~~CVD, CE Specific~~	~~Critical~~	~~Guidance/Evaluation~~	
N01467	Statistical data mining to provide alternative clinical trial designs for PREP Evaluation	Liang, Q.	Clinical Evaluation	CE Specific	Critical	Guidance/Evaluation	
N01468	Statistical approaches for developing overall exposure reduction scores	Liang, Q.	Clinical Evaluation	CE Specific	Priority	Evaluation	
N01470	Longitudinal Clinical Risk Evaluation Study Design	Roethig, H	Clinical Evaluation	Cancer, CVD, COPD, CE Specific	Critical	Evaluation	
N01479	Surveillance Guidelines	Adams, C	Clinical Evaluation	CE Specific	Critical	Guidance	

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N01482	Compensation Consensus	Roethig, H	Clinical Evaluation	CE Specific	Critical	Guidance	

Clinical Evaluation Publication Projects

	Title	Leader	Authors	Functional Area	Priority	Deliverable	Notes
N01337	Multi-Center Total Exposure Study	Roethig, H	Kinser, Adams, Nelson, Sarkar, Oey, Feng, Stabbert, Rustemeier	Clinical Evaluation	Critical	Publication	
N01351	AHR Exhaled Breath Measurements in Humans	Major, T		Clinical Evaluation	Priority	Publication	No Manuscript planned suggested to delete by CE
N01401	Exercise Performance of Adults Smoking ACCORD or Conventional Cigarettes	Unverdorben, M.	2004	Clinical Evaluation	Critical	Publication	
N01402	Influence of Smoking the EHCSS ACCORD® on Endothelium-Dependent Venoreactivity	Unverdorben	2005	Clinical Evaluation	Critical	Publication	Project Delayed by Management
N01455	Assessment of exercise performance of non/no-smokers exposed to ETS	Unverdorben, M.		Clinical Evaluation	Priority	Publication	Project Delayed by Management
N01456	Non-linear modeling of biomarkers from the Multi-Center Total Exposure Study	Nelson, B		Clinical Evaluation	Priority	Publication	
N01457	Method Development for the Long Term Studies	Nelson, B		Clinical Evaluation	Critical	Publication	
N01459	TES Follow-up Study	Oey, J		Clinical Evaluation	Critical	Publication	
N01460	Characterization of enzyme induction as an early biomarker of potential harm	Sarkar, M.	2004	Clinical Evaluation	Priority	Publication	
N01463	Selected Biomarkers of Exposure and Potential Harm in Adult Smokers of 3.0 – 6.9 mg tar (FTC) Cigarettes and Non-smokers	Kinser, R.	Internal/External Authors: R. Kinser, B. Nelson, J. Oey, R. Walk, J.-J. Roethig, G. Schepers, A.R. Tricker, PMI; K. Rustemeier, PMRL GmbH; B. Zedler	Clinical Evaluation	Critical	Publication	

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